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Proposed Maximum Residue Limit PMRL2016-68

Formetanate Hydrochloride

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing revisions to the maximum residue limits (MRLs) of the registered technical grade formetanate hydrochloride established under the *Pest Control Products Act* for nectarines and citrus fruits.

As a result of the 2008 re-evaluation of formetanate hydrochloride, the PMRA has received field trials on nectarines and citrus fruits in order to propose amendments to the current Canadian MRLs under the *Pest Control Products Act* for these commodities such that the MRLs reflect the revised use pattern. The evaluation of these field trials indicated that they are scientifically acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally specified as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

The PMRA is proposing to specify MRLs for formetanate hydrochloride on oranges, lemons, limes, grapefruit, tangelos and tangerines to permit the import and sale of food containing such residues. The PMRA has determined the quantity of residues that are likely to remain in or on the imported commodities when formetanate hydrochloride is used according to label directions in the exporting country, and that such residues will not be a concern to human health.

Consultation on the proposed MRLs for formetanate hydrochloride is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by Canada's Notification Authority and Enquiry Point.

The proposed MRLs for formetanate hydrochloride are as follows.

Table 1 Proposed Maximum Residue Limits for Formetanate Hydrochloride

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity[2,3]
Formetanate hydrochloride	*N,N*-dimethyl-*N'*-[3-[[(methylamino)carbonyl]oxy]phenyl] methanimidamide hydrochloride (1:1)	0.9	Orange
		0.4	Grapefruit
		0.09	Lemon
		0.03	Lime, tangelo, tangerine
		0.02	Nectarine

[1] ppm = parts per million
[2] It is proposed that the MRL of 4 ppm currently established for "citrus fruits" be replaced by commodity specific MRLs. MRLs are not being established for all imported commodities in crop group 10 since the use in the US is limited to oranges, lemons, limes, grapefruit, tangelos and tangerines.
[3] It is proposed that the MRL of 3 ppm currently established for nectarines be revised to 0.02 ppm.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

The MRLs proposed for formetanate hydrochloride in Canada are the same as corresponding American tolerances, except for nectarine, orange, grapefruit and lemon, in accordance with Table 2. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs[1] listed for formetanate hydrochloride in or on any commodity on the Codex Alimentarius Pesticide Residues in Food and Feed webpage.

As the registrant has also cancelled uses on apples, peaches and pears in the US (2011) and in Canada (2012), and the use on plums is no longer permitted in the US, the existing MRLs of 3 ppm for apples, peaches and pears, and 0.5 ppm for plums are proposed for revocation. Following the revocation of these MRLs, these crops will be regulated under subsection B.15.002(1) of the Food and Drugs Regulations, which requires that residues not exceed the General MRL (GMRL) of 0.1 ppm. The PMRA does not anticipate any trade implications given that there are also no Codex MRLs for formetanate hydrochloride.

The field trials reflecting the revised use pattern for formetanate hydrochloride on nectarines and citrus fruits are being reviewed concurrently in Canada and the United States. Once reassessed, the American tolerances for formetanate hydrochloride will be listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Orange	0.9	1.5	Not established
Grapefruit	0.4	1.5	Not established
Lemon	0.09	0.6	Not established
Nectarine	0.02	0.4	Not established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for formetanate hydrochloride up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for formetanate hydrochloride in nectarines, grapefruit, lemons, and oranges were submitted to support the revised use pattern for these crops as a result of the 2008 re-evaluation of this chemical.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for formetanate hydrochloride was based upon the residues observed in crop commodities treated according to label directions, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs.

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

Commodity	Application Method/ Total Application Rate (g a.i./ha)[1]	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)
Nectarines	1.28–1.32	80–160	<0.02	<0.02
Orange	1.28–1.31	29–30	0.110	0.451
		171–264	<0.02	0.0214
Grapefruit	1.29–1.43	30	0.062	0.195
Lemon	1.27–1.29	186–207	0.014	<0.02

[1] g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of formetanate hydrochloride. Residues of formetanate hydrochloride in these imported crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.